

Clinical Evaluation of the Efficacy of Gomutra Aasava in Shvitra Vis-A-Vis Vitiligo.

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Abstract: Vitiligo is an acquired depigmenting skin condition that results from the destruction of melanocytes. It is a progressive, idiopathic pigmentation skin disorder, characterized by hypopigmented patches. The Vedic texts have even mentioned the term 'Kilasa' or Shvitra to describe hypopigmented patches. According to Ayurveda, Shvitra is caused by improper diet and behavioral factors. Certain other factors like Daivakrita nidana, beejadushti nidana and nidana-arthakar vyadhis are known to induce Shvitra. Many Ayurvedic medicines are known to regenerate melanocytes among which Gomutra Aasava is the one. The present paper deals with the clinical evaluation of the efficacy of Gomutra Aasava in Shvitra.

Keywords: Shvitra, Vitiligo, Gomutra, Aasava.

I. Introduction:

Vitiligo is a pigmentation disorder having multifactorial origin eg. Genetic-endocrine-nutritional factors; chemical and pharmacologic agents, physical agents. A milky white or ivory white depigmented patch, generally lined by a rim of hyperpigmentation appear on scalp, retro-auricular folds, upper eye-lids, lips, fingertips, palms, nipples, waist, scrotum, glans, legs, toe-tips and soles. Teenagers are normally affected. Etiology of vitiligo can be summarised as follows^{1,2,3} :-

- a) Neural Concept :- Peripheral nerve-endings secrete cytotoxic substances viz. melatonin which damages the melanocytes.
- b) Auto-Immune Mechanism :- Antibodies against melanin have been isolated from the serum of vitiligo patients. Hence, vitiligo is an auto-immune disorder.
- c) Melanocyte Exhaustion Theory :- Due to the continuous strain of producing melanin, the melanocytes get exhausted resulting into vitiligo.

Amongst various theories, Auto-Immune concept for disseminated Vitiligo and neural concept for segmental vitiligo are widely accepted. Gomutra Aasava contains Shunthi, Maricha, Pippali, Chitraka, Madhu and Gomutra^{4,5,6}.

Gomutra asava being Aampachak reduces dhatu-samata. Due to Strotomukha-Vishodhana the Vimargagamit doshas are placed back in their Original Sthanas. Being Kapha-Vata shamak, it balances the vitiated Kapha dosha.

Gomutra asava stimulates liver and spleen; thereby regulating the function of Pachaka Pitta, Ranjakapitta and Bhrajakapitta. It also acts as a Raktaprasadana dravya.

Being Yogavahi (catalyst) it acts fastly, hence Gomutra Asava was selected to evaluate its role in treating Shvitra-vis-a-vis vitiligo.

II. Aims and Objectives:

- 1) To study the etiopathogenesis of Shvitra vis-a-vis Vitiligo in detail.
- 2) To evaluate the efficacy of Gomutra Asava in pigment regeneration in vitiligo.

III. Materials and Methods:

This was a randomized clinical trial conducted in experimental group at Dept. of Kayachikitsa of Shri Ayurved Mahavidyalaya, Nagpur⁷.

A total of 46 uncomplicated symptomatically diagnosed cases of shvitra were studied during this research work.

IV. Inclusion Criteria:

Diagnosed cases of uncomplicated vitiligo, either segmental or generalized, of both the sexes in the age group of 8 to 70 years were registered.

V. Exclusion Criteria:

- 1) Vitiligo associated with malignant melanoma, albinism & other skin-diseases.
- 2) Pregnancy (Chitraka causes uterine contractions, hence avoided in patients with Pregnancy)
- 3) PNC & lactating mother (effects not fully studied in infants)

VI. Assessment Criteria:

a) Surface area of Hypopigmented patches was measured with the help of Trace-Paper and Graph Paper.

b) Colour-Change in Patches -

International Protocol for Grading of Repigmentation :-

Grade 1 - Diffuse lightening usually seen at margins (tan colour)

Grade 2 - Perifollicular repigmentation

Grade 3 - Spreading of Perifollicular repigmentation

Grade 4 - Coalescing pigmentation with areas of depigmentation in between.

Grade 5 - Confluent repigmentation with remnant islets of depigmentation in between.

Grade 6 - Complete repigmentation.

Note :- These grades should be applied to a single predetermined representative macule on various body parts.

c) Colour & Patches :-Shweta (Depigmented/White), Mishra (Trichrome), Tamra(Coppery/Hypopigmented), Rakta (Red/Pink).

d) Colour of Hair in a depigmented Patch: Total loss of Hair; white (Shuklavarna), whitish (ashuklavarna), black.

e) Burning and Itching in the Patches were also noted as +, ++, +++, +++++ according to their intensity.

f) Relief (Upashaya) was assessed by noting changes in the surface area of Patches -

No relief - 0 %

Good relief - 1-25 %

Better relief - 26-50 %

Best relief - 51-75 %

Excellent relief - 76-99 %

Total relief - 100 %

Duration of Trial :-6 months with monthly follow-ups.

Trial Drug :-

Gomutra Asava - Ingredients.

Gomutra (Cow's Urine) - 100 Ltr.

Chitraka (Plumbago zeylanica) - 960 g.

Shunthi (Zingiber officinale) - 960 g.

Maricha (Piper nigrum) - 960 g.

Pippali (Piper longum) - 960 g.

Madhu (Honey) - 19.230 kg.

All these ingredients were mixed and fermented for 15 days. After having Sandhana-Pariksha, the product was filtered and dispensed to the patients of experimental group.

Gomutra Asava :-

pH - Neutral

Alcohol Content - 4 % - 4.5 %

Sugars - Reducing type

Alkaoids - Present

Route of Drug Administration - Orally, twice a day after meals with equal volume of water.

Dosage :- 6-12 yr. - 20 ml / 2 doses

13-60 yr. - 40 ml / 2 doses

above 60 yr. - 30 ml / 2 doses.

VII. Observation & Results:

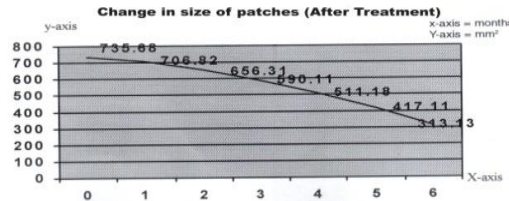
Post treatment Laboratory findings

	Hb%	TLC	DLC			ESR	
			P	L	E		M
\bar{x} =	1.5630	-558.6966	1.5217	1.3913	-1.2173	-0.4347	-6.7608
SD	1.0152	1402.391	8.9832	7.5438	2.9658	2.4913	7.7062
$SE = \frac{SD}{\sqrt{n}}$	0.1496	206.771	1.3245	1.122	0.4372	0.3673	1.1362
$t_{cal} = \frac{\bar{x} - \mu}{SE}$	10.4478	1.702	1.1488	1.2509	2.7843	1.1835	5.9503
Significance	Highly Significant at P<0.001	significant at P<0.01	Not Significant even at P<0.1	Not Significant even at P<0.1	Significant at P<0.01	Not Significant at P<0.1	Highly significant at P<0.001

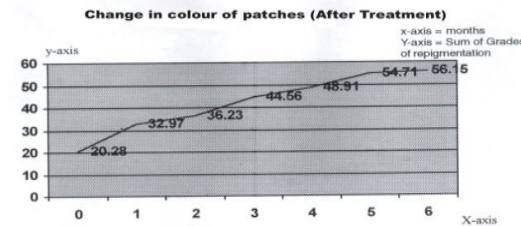
Change in size of patches (after treatment)

	X_0 = $X_1 - X_2$	X_1 = $X_2 - X_3$	X_2 = $X_3 - X_4$	X_3 = $X_4 - X_5$	X_4 = $X_5 - X_6$	X_5 = $X_6 - X_7$	X_6 = $X_7 - X_8$
\bar{X} =	28.8636	50.5	66.2045	77.1777	94.0681	104.2045	422.5454
SD	29.6268	37.4206	44.0547	60.6068	72.1179	84.4115	289.5240
$SE = \frac{SD}{\sqrt{n}}$	4.3682	5.5173	6.4955	8.9359	10.6332	12/4457	42/6879
$t_{95} = \frac{\bar{X}}{S.E.}$	6.6076	9.153	10.1923	8.6368	8.8466	8.3727	9.8984
Significance	P<0.001	P<0.001	P<0.001	P<0.001	P<0.001	P<0.001	P<0.001

X_1-X_8 , are the reading at 0,1,2,3,4,5,6 months respectively



Months	0	1	2	3	4	5	6
Mean (mm ²)	735.68	706.82	656.31	590.11	511.18	417.11	313.13



Months	0	1	2	3	4	5	6
(Grades%)	20.28	32.97	36.23	44.56	48.91	54.71	56.15

- The youngest patient was a 8 year old male and the oldest patient was a female of 70 years. However in the age-group of 11-20 years occurrence was highest (23.9 %) and in (1-10) yr, group it was lowest (2.17 %)
- Family history was observed in 4 patients (8.69 %)
- Vatapittaja Prakriti (45.65 %), Kaphapittaja Prakriti (43.48 %) were noted.
- Vitiligo Vulgaris (bilaterally symmetrical patches) observed at bony prominences of arms & legs; face, neck and axilla - 45.65 %
- Changes in size of patch - Mean (mm²) at 0 months was 735.68 mm². After treatment of 6 months mean was 313.13 mm² (P<0.001)
- Changes in Colour of Patch: - Grades (%) at 0 months were 20.28 grade %. After treatment of 6 months, grade % was 56.15 % (P<0.001)
- Haemoglobin level raised (P<0.001)
- ESR lowered (P<0.001)
- TLC (Eosinophils) lowered (P<0.01)
- No significant changes were observed in Polymorphs, Lymphocytes and Monocytes (P>0.01)
- Leucoderma Patches due to burn - No relief (0 %)
- Family history - Four patients Result % and relation with vitiligo patients are as follows - 0 % (Sister), 28.75% (Mother), 61.53 % (Sister), 65.60 % (Sister)
- Allergic leucoderma Patches - Result % and cause of allergy -Two Patients had allergic leucoderma Patient No. (1) - 89.69 % relief (Metallic wrist watch belt was changed to a rubber belt). Patient No. (2) - 90.00 % (Constrict use of a branded lip-stick)
- **Duration of Illness :-**
Upto 1 yr. - relief % was 70 % and neural concept for segmental vitiligo.....more than 1 yr. - relief % was 19.44 %.
- Exposed areas of the body involved and best relief %
Forearms (100 %); Wrist joints (31.33 %); Palms (30.77 %); Soles (6.8 %); Face (18.56 %); Elbow joints (14.76 %); Neck (11.93 %); Chest/Abdomen (11.92 %); Thighs (19.84 %).

VIII. Discussion:

Vitiligo is an acquired, progressive, idiopathic depigmenting skin condition. Amongst various theories, Auto-Immune theory for disseminated vitiligo and neural concept for segmental vitiligo are widely accepted theories.

According to Ayurvedic texts; lasika, rakta and mamsa are vitiated in shvitra. Excessive use of Kaphaja Ahara and Vihara leads to the obstruction of Strotasas.

Gomutra asava due to its Katurasa, Katuvipaka and Ushnaviryā removes the obstruction of strotasas and also normalises the function of Pachakapitta. Ultimately, ranjakapitta and bhrajakapitta. function normally, thereby repigmenting the hypopigmented patches. In short, it acts on liver and spleen (Raktashaya) as can be observed by raised Hb % $P<0.001$; low ESR $P<0.001$; Low TLC $P<0.01$; Low Eosinophils $P<0.01$ and colour change in patches $\chi^2 P<0.001$.

IX. Conclusion:

According to Ayurvedic texts, Shvitra is an Krichhrasadhya Vyadhi, having Kaphadushti as a most important factor. Improper diet and behavioural factors precipitate Shvitra. Shvitra can be correlated with vitiligo.

A Clinical trial with oral administration of Gomutra Aasava containing Shunthi, Maricha, Pippali, Chitrak, Madhu and Gomutra proved that the formulation is a safe remedy with significant repigmentation property.

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